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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,348	01/19/2001	Dewen Qiu	19603/2986 (CRF D-1940B)	7683

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Michael L. Goldman
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603

EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,348	QIU ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-47,49-54,58-73,75-77 and 80-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-47,49-54,58-73,75-77 and 80-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 41-47, 49-54, 58-73, 75-77 and 80-85 are pending

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to claims 48, 54, 68, 74 and 78-79 informalities is obviated by their cancellation.

4. The rejections of claims 41-54 and 58-79 under 35 U.S.C. 102(e) as being anticipated by Bauer et al (US Patent 5,850,015, filed June 1995), claims 41-54 and 58-79 under 35 U.S.C. 102(e) as being anticipated by Beer et al (US Patent 6,174,717, filed July 1992), and claims 41-54 and 58-79 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 5,850,015 are withdrawn in light of Applicant's amendment to the claims to specify that the nucleic acid encoding the hypersensitive response elicitor is not pathogen-inducible.

Claim Rejections - 35 USC § 112

5. Claims 41-47, 49-54, 58-73, 75-77 and 80-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "promoter that is not pathogen-inducible" in claims 41, 61 and 75, line 5. The only reference to plant promoters in the specification, on pg 36, line 19, states "various promoters including pathogen-induced promoters". Thus, at the time of filing, the only promoters contemplated were pathogen-induced promoters or promoters in general, which included pathogen-induced ones. All promoters other than pathogen-induced ones were not part of the originally filed invention.

Thus, such a phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

6. Claims 41-47, 49-54, 58-73 and 75-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 February 2004, as applied to claims 41-54 and 58-79. Applicant's arguments and the Declaration of Wei, both filed 16 August 2004 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would recognize that they were in possession of the claimed invention at the time of filing because the four exemplary species were recognized at the time of filing as belonging to an art-recognized class of bacterially encodes hypersensitive response eliciting proteins (response pg 8-9).

This is not found persuasive. No nucleic acids encoding hypersensitive response elicitors from any of the at least 68 *Xanthomonas* species, from any of the at least 12 *Erwinia* species other than *E. carotovora* and *E. chrysanthemi*, or from any of the at least 113 *Pseudomonas* species other than *P. syringae* and *P. solanacearum* were described. Thus, no written description exists for any nucleic acid encoding a hypersensitive response elicitor from any except the four exemplified species. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at pg 1939:

> Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. §112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description , in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

Because no written description exists for any nucleic acid encoding a hypersensitive response elicitor from any *Xanthomonas* species, from any of the at least 12 *Erwinia* species other than *E. amylovora* and *E. chrysanthemi*, or from any of the at least 113 *Pseudomonas* species other than *P. syringae* and *P. solanacearum*, no written description exists for any method of using such nucleic acids. See *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC 2004) at page 1894:

> Rochester also attempts to distinguish Fiers, Lilly, and Enzo by suggesting that the holdings in those cases were limited to composition of matter claims, whereas the '850 patent is directed to a method. We agree with the district court that that is "a semantic distinction without a difference." Univ. of Rochester, 249 F. Supp. 2d at 228. Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment."

Furthermore, the existence of three other hypersensitive response elicitors from *E. amylovor*, DspE, DspF and HrpW, as cited in a prior Office action, demonstrates that even within a single species, description of only one such nucleic acids fails to describe nucleic acids encoding hypersensitive response elicitors within the full scope of the claims.

Applicant urges that hypersensitive response elicitors from one species are often homologous to hypersensitive response elicitors from other members of the same genus (response pg 9).

This is not found persuasive. Alfano et al (1997, J. Bacteriol. 179:5655-5662), cited in the Declaration, states that there are homologous hrp genes that do not lead to a hypersensitive response (pg 5656, left column, paragraph 1). The specification does not describe the structural features that distinguish hypersensitive response elicitors that result in a hypersensitive response from those that are not.

The Declaration states that a nucleic acid encoding a hypersensitive response elicitor from one species and be used to isolate hypersensitive response elicitors from other species and other strains, citing Bauer et al, Cui et al, Ahmad et al, Jock et al and Preston et al (Declaration ¶6-11).

This is not found persuasive because this does not describe the structural features of those nucleic acids or nucleic acids encoding hypersensitive response elicitors from any *Xanthomonas* species, from any of the at least 12 *Erwinia* species other than *E. carotovora* and *E. chrysanthemi*, or from any of the at least 113 *Pseudomonas* species other than *P. syringae* and *P. solanacearum*.

Applicant urges that the disclosed species are representative of the claimed genus because genes encoding hypersensitive response elicitors are similarly regulated, expressed and secreted by their source organisms, and thus one of skill in the art would expect them to behave the same (response pg 9).

This is not found persuasive because gene regulation and expression are the functional of regulatory sequences not part of the coding region of the gene, and thus not part of the claimed nucleic acid encoding hypersensitive response elicitor. Furthermore, the structural features leading to secretion of the protein are not described, and at any rate would only amount to a description of a small portion of the protein. Lastly, similar regulation, expression and secretion of

The Declaration states that hrp genes are clustered, citing Bonas et al, Alfano et al, and Sawnson et al, and substantially all known hypersensitive response elicitors are secreted through the type III hrp dependent secretion pathway, citing Bogdanove et al, Alfano et al, Wei et al, and Bonas et al (Declaration ¶12-15).

This is not found persuasive. That not all known hypersensitive response elicitors are secreted through the type III hrp dependent secretion pathway refutes Applicant's arguments that secretion through the type III hrp dependent secretion pathway is a description feature of hypersensitive response elicitors

The Declaration states that hypersensitive response elicitors have a number of common characteristics, including being glycine rich, heat stable, hydrophilic, lacking an N-terminal

signal sequence and susceptible to proteolysis and having a unique secondary structure, citing Bonas, Bonas et al, Gopalan et al, Alfano et al and Fan et al (Declaration ¶16-17).

This is not found persuasive. Many unrelated proteins are glycine rich, heat stable, hydrophilic, lacking an N-terminal signal sequence and susceptible to proteolysis. The specification does not describe any unique secondary structure of hypersensitive response elicitors.

Applicant urges that the disclosed species are representative of the claimed genus because they share the ability to induce specific plant responses, including disease resistance, growth enhancement and stress resistance (response pg 10). The Declaration expands on this, citing Wei et al, and Alfano et al and presents experimental data (Declaration ¶18-31).

This is not found persuasive because written description requires more than a functional description of the claimed species. Furthermore, Alfano et al teaches "... analysis of harpins from other bacteria has revealed that harpins differ substantially in their primary structure and their contribution to Hrp phenotypes, and their actual function is unknown" (pg 5658, left column, paragraph 1).

Applicant urges that the Office did not demonstrate that the genus contains structurally and functionally unrelated species (response pg 10-11).

This is not found persuasive. Alfano et al teaches that he genus contains structurally and functionally unrelated species (pg 5656, left column, paragraph 1; pg 5658, left column, paragraph 1).

7. Claims 41-47, 49-54, 58-73 and 75-77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using nucleic acids encoding hypersensitive response elicitors of SEQ ID NOs:2, 4, 6 and 8 to impart pathogen resistance to plant, does not reasonably provide enablement for methods of using nucleic acids encoding any hypersensitive response elicitors to impart pathogen resistance to plant or for propagation of some plants by seed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 February 2004, as applied to claims 41-54 and 58-79. Applicant's arguments and the Declaration of Wei, both filed 16 August 2004 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art can identify other nucleic acids encoding hypersensitive response elicitors, transforming plants with them and ascertaining whether they are disease resistant, citing Declaration ¶5-11, 21 and 28-30 (response pg 11).

This is not found persuasive because the specification must teach these nucleic acids.

Applicant urges that breeders establishing new commercial varieties would use seed propagation for plants that are normally propagated by cuttings (response pg 11-12).

This is portion of the rejection is withdrawn.

8. Claims 52 and 72 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that

Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 February 2004. Applicant's arguments filed 16 August 2004 have been fully considered but they are not persuasive.

Claims 52 and 72 appear to not further limit parent claims 41 and 61, respectively. The claims are drawn to the method of imparting pathogen resistance to plants by providing plants transformed with nucleic acid encoding a hypersensitive response elicitor; however, nucleic acid encoding a hypersensitive response elicitor inherently confer resistance to viruses, bacteria, fungi and combinations thereof. If however, only some nucleic acids encoding hypersensitive response elicitor confer resistance to viruses, bacteria, fungi and combinations thereof this rejection does not apply.

Applicant urges that the recited species are narrower than "pathogen" (response pg 12).

This is not found persuasive because there are no other plant pathogens other than viruses, bacteria, and fungi.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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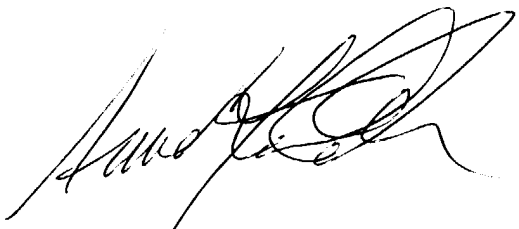
Anne R. Kubelik, Ph.D.
October 27, 2004



ANNE KUBELIK
PATENT EXAMINER